# Senate Bill No. 891

## CHAPTER 295

An act to add and repeal Section 1256.01 of the Health and Safety Code, relating to public health.

[Approved by Governor September 25, 2008. Filed with Secretary of State September 25, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 891, Correa. Health facilities: Elective Percutaneous Coronary Intervention (PCI) Pilot Program.

Existing law provides for the licensure and regulation of health facilities by the State Department of Public Health. Existing law authorizes health facilities to engage in various types of cardiac intervention and surgery.

This bill, until January 1, 2014, would establish the Elective Percutaneous Coronary Intervention Pilot Program in the department, which would authorize up to 6 eligible acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet prescribed, additional criteria to perform scheduled, elective primary percutaneous coronary intervention (PCI), as defined, for eligible patients.

*The people of the State of California do enact as follows:*

SECTION 1. The Legislature finds and declares all of the following:

(a) Hospitals in California with cardiac catheterization laboratory service and without cardiac surgery services are currently limited to performing certain diagnostic and unscheduled interventional procedures. These parameters were established by the Legislature over 20 years ago, when interventional cardiology was in its infancy, as a precautionary measure against complications.

(b) Technological and methodological advances in interventional cardiology have greatly improved patient outcomes.

(c) Multiple studies have demonstrated that performance of primary and elective percutaneous coronary intervention (PCI) in hospital-based cardiac catheterization laboratories, with offsite cardiac surgery backup, results in numerous benefits to patients, including all of the following:

(1) Improved patient outcomes due to the correlation between the volume of procedures performed and the outcome. For example, as patient volume increases, patient outcomes improve.

(2) Provision of diagnosis and therapeutic treatment in one procedure at one hospital, instead of two procedures at two different hospitals.

(3) Improved access to care and continuity of care since patients may undergo interventional cardiology procedures closer to home.

(4) Reduction of pressure to create and maintain low-volume cardiac surgery centers primarily to support interventional cardiology, thus allowing for a better allocation of resources.

(d) Economic benefits associated with shorter hospital stays and reduced numbers of discharges and transfers indicate that elective PCI at hospitals with offsite cardiac surgery backup is a cost-effective alternative to limiting elective PCI to hospitals with onsite cardiac surgery.

(e) Primary PCI is the treatment of choice for ST segment elevation myocardial infarction (STEMI) patients, however it should be performed within a 90-minute window of time. Upon arrival in many emergency rooms, STEMI patients often do not receive primary PCI because it is not available in that hospital, and hospital-to-hospital transfer cannot be accomplished within the optimal 90-minute door-to-balloon time. Among the factors affecting achievement of this benchmark is the experience level of the hospital and its staff, and the difficulty of providing coverage 24 hours per day, 365 days per year. One strategy for overcoming these factors, and thus improving access to lifesaving PCI, is to permit hospitals capable of performing PCI to perform both primary and elective PCI. Higher total PCI volumes will increase the experience and capabilities of the facility, interventional cardiologists, and personnel, resulting in improved outcomes.

(f) The American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) issued a report titled “2005 Guidelines Update for Percutaneous Coronary Intervention.” The ACC/AHA/SCAI guidelines acknowledge that several centers with offsite cardiac surgery backup have reported satisfactory results in performing elective PCI based on careful case selection and well-defined arrangements for immediate transfer to a surgical program if needed. Nevertheless, the ACC/AHA/SCAI guidelines do not recommend elective PCI without onsite cardiac surgery, but note that this recommendation may be subject to revision as clinical data and experience increase.

(g) After publication of the ACC/AHA/SCAI guidelines, the SCAI issued recommendations for performing elective and primary PCI in hospitals without onsite cardiac surgery in recognition of the reality that elective PCI without onsite cardiac surgery is already performed in 28 states and around the world without regard to whether cardiac surgery backup is available onsite or offsite.

(h) Due to the unique demographics and distribution of California’s population, the Legislature finds that it is appropriate to gather clinical data and experience regarding elective PCI in hospitals with offsite cardiac surgery backup in order to enable California licensed health care facilities and physicians to maintain the highest standard of health care for Californians. For the foregoing reasons, it is the intent of the Legislature to establish the Elective Percutaneous Coronary Intervention (PCI) Pilot Program to allow general acute care hospitals that are licensed to perform

cardiac catheterization laboratory service in California, and that meet additional rigorous requirements, to also perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

SEC. 2. Section 1256.01 is added to the Health and Safety Code, to read:

1256.01. (a) The Elective Percutaneous Coronary Intervention (PCI) Pilot Program is hereby established in the department. The purpose of the pilot program is to allow the department to authorize up to six general acute care hospitals that are licensed to provide cardiac catheterization laboratory service in California, and that meet the requirements of this section, to perform scheduled, elective percutaneous transluminal coronary angioplasty and stent placement for eligible patients.

(b) For purposes of this section, the following terms have the following meanings:

(1) "Elective Percutaneous Coronary Intervention (elective PCI)" means scheduled percutaneous transluminal coronary angioplasty and stent placement. Elective PCI does not include urgent or emergent PCI that is scheduled on an ad hoc basis.

(2) "Eligible hospital" means a general acute care hospital that has a licensed cardiac catheterization laboratory and is in compliance with all applicable state and federal licensing laws and regulations.

(3) "Interventionalist" means a licensed cardiologist who meets the requirements for performing elective PCI at a pilot hospital.

(4) "Pilot hospital" means a hospital participating in the Elective Percutaneous Coronary Intervention (PCI) Pilot Program established by this section.

(5) "Primary percutaneous coronary intervention (primary PCI)" means percutaneous transluminal coronary angioplasty and stent placement that is emergent in nature for acute myocardial infarction and that is performed before administration of thrombolytic agents.

(6) "Receiving hospital" means a licensed general acute care hospital with cardiac surgery services that has entered into a transfer agreement with a pilot hospital.

(7) "STEMI" means ST segment elevation myocardial infarction, a type of heart attack, or myocardial infarction, that is caused by a prolonged period of blocked blood supply, which affects a large area of the heart muscle, and causes changes on an electrocardiogram and in the blood levels of key chemical markers.

(8) "Transfer agreement" means an agreement between the eligible hospital and the receiving hospital that meets all of the requirements of this section.

(c) To participate in the pilot program, an eligible hospital shall demonstrate that it complies with the recommendations of the SCAI for performance of PCI without onsite cardiac surgery, as those recommendations may evolve over time, and meets all of the following criteria:

(1) Performs at least 36 primary PCI procedures annually, has the capacity to perform at least 200 primary and elective PCI procedures annually, and by year two of participation in the pilot program, actually performs at least 200 primary and elective procedures, including at least 36 primary PCI procedures.

(2) Has an on-call schedule with operation of the cardiac catheterization laboratory 24 hours per day, 365 days per year.

(3) Performs primary PCI as the treatment of first choice for STEMI, and has policies and procedures that require the tracking of door-to-balloon times, with a goal of 90 minutes or less, and requires that outlier cases be carefully reviewed for process improvement opportunities.

(4) Permits only interventionists who meet the following requirements to perform elective PCI under the pilot program:

(A) Perform at least 100 total PCI procedures per year, including at least 18 primary PCI per year.

(B) Have lifetime experience of at least 500 total PCI procedures as primary operator.

(C) Have complication rates and outcomes equivalent or superior to national benchmarks established by the American College of Cardiology.

(D) Hold board certification by the American Board of Internal Medicine in Interventional Cardiology and Cardiovascular Diseases.

(E) Actively participate in the eligible hospital's quality improvement program.

(5) Employs experienced nursing and technical laboratory staff with training in interventional laboratories. Cardiac catheterization laboratory personnel must have demonstrated competency treating acutely ill patients with hemodynamic and electrical instability.

(6) Employs experienced intensive care unit nursing staff who have demonstrated competency with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Nursing personnel must be capable of managing endotracheal intubation and ventilator management both onsite and during transfer, if necessary. The eligible hospital shall demonstrate sufficient staffing capacity in the intensive care unit to provide posttreatment care for patients undergoing elective PCI.

(7) Has a well-equipped and maintained cardiac catheterization laboratory with high resolution digital imaging capability and intraaortic balloon pump support compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data via T-1 transmission line as well as audio and video images to review terminals for consultation at the receiving hospital is ideal.

(8) Has an appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, throbectomy and distal protection devices, covered stents, temporary pacemakers, and pericardiocentesis trays. Pressure wire devices and intravascular ultrasound equipment are optimal, but not mandatory.

(9) Provides evidence showing the full support from hospital administration in fulfilling the necessary institutional requirements, including, but not limited to, appropriate support services such as respiratory care and blood banking.

(10) Has a written transfer agreement for the emergency transfer of patients to a facility with cardiac surgery services. Transport protocols shall be developed and tested a minimum of twice per year, and must ensure the immediate and efficient transfer of patients, within 60 minutes, 24 hours per day, seven days per week, from the eligible hospital to the receiving hospital. The time for transfer of patients shall be calculated from the time it is determined that transfer of a patient for emergency cardiac surgery is necessary at the eligible hospital, to the time that the patient arrives at the receiving hospital.

(11) Has onsite rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.

(12) Participates in the American College of Cardiology-National Cardiovascular Data Registry.

(13) Provides evidence in its application that demonstrates the use of rigorous case selection for patients undergoing elective PCI. Patient selection criteria will meet all of the following requirements, or otherwise be consistent with the recommendations of the SCAI, as those recommendations may evolve.

(A) Patient selection shall be based on the interventionalist's professional medical judgment, which may include, but is not limited to, consideration of the patient's risk, the patient's lesion risk, and the patient's overall health status.

(B) For purposes of this section, "patient risk" means the expected clinical risk in case of occlusion or other serious complication caused by the procedure. "High patient risk" may include, but is not limited to, patients with any of the following features: decompensated congestive heart failure (Killip class 3) without evidence for active ischemia, recent cardiovascular attack, advanced malignancy, known clotting disorders; left ventricular ejection fraction less than or equal to 25 percent; left main stenosis greater than or equal to 50 percent or three-vessel disease unprotected by prior bypass surgery greater than 70 percent stenosis in the proximal segment of all major epicardial coronary arteries; single target lesion that jeopardizes over 50 percent of remaining viable myocardium.

(C) For purposes of this section, "lesion risk" means the probability that the procedure will cause acute vessel occlusion or other serious complication. "High lesion risk" may include, but is not limited to, lesions in open vessels with any of the following characteristics: diffuse disease (greater than 2 cm in length) and excessive tortuoisty of proximal segments; more than moderate calcification of a stenosis or proximal segments; location in an extremely angulated segment (greater than 90 percent); inability to protect major side branches; degenerated older vein grafts with friable lesions; substantial thrombus in the vessel or at the lesion site; and any other feature that may, in the interventionalist's judgment, impede stent deployment.

(D) In evaluating patient risk and lesion risk to determine patient eligibility for inclusion in the pilot program, the interventionalist shall apply the strategy set forth by the SCAI as set forth below, or as it may otherwise evolve:

(i) A high-risk patient with a high-risk lesion shall not be included in the pilot program.

(ii) A high-risk patient with a not high-risk lesion may be included in the pilot program upon confirmation that a cardiac surgeon and an operating room are immediately available if necessary.

(iii) A not high-risk patient with a high-risk lesion may be included in the pilot program.

(iv) A not high-risk patient with a not high-risk lesion may be included in the pilot program.

(14) Will include evidence of institutional review board (IRB) approval of its participation in the pilot program for as long as ACC/AHA/SCAI guidelines categorize elective PCI with offsite cardiac surgery as a Class III indication.

(15) Shall demonstrate evidence of the process for obtaining written informed consent from patients prior to undergoing elective PCI. The application shall include a copy of the eligible hospital's informed consent form applicable to elective PCI. Evidence of IRB approval of the informed consent form will also be provided for as long as ACC/AHA/SCAI guidelines categorize elective PCI with offsite cardiac surgery a Class III indication.

(d) Consistent with this section, the department shall invite eligible hospitals to submit an application to participate in the Elective PCI Pilot Program. The applications shall include sufficient information to demonstrate compliance with the standards set forth in this section, and additionally include the effective date for initiating elective PCI service, the general service area, a description of the population to be served, a description of the services to be provided, a description of backup emergency services, the availability of comprehensive care, and the qualifications of the general acute care hospital providing the emergency treatment. The department may require that additional information be submitted with the application. Failure to include any required criteria or additional information shall disqualify the applicant from the application process and from consideration for participation in the pilot program. The department may select up to six general acute care hospitals for participation in the Elective PCI Pilot Program based on the applicant's ability to meet or exceed the criteria described in this section.

(e) An advisory oversight committee comprised of one interventionalist from each pilot hospital, an equal number of cardiologists from nonpilot hospitals, and a representative of the department shall be created to oversee, monitor, and make recommendations to the department concerning the pilot program. In designating the cardiologists from nonpilot hospitals to the committee, the department shall consider the recommendations of the California Chapter of the American College of Cardiology. The advisory oversight committee shall submit at least two reports to the department

during the pilot period. The oversight committee shall conduct a final report at the conclusion of the pilot program, including recommendations for the continuation or termination of the pilot program.

(f) If at any time a pilot hospital fails to meet the criteria set forth in this section for being a pilot hospital or fails to safeguard patient safety, as determined by the department, that pilot hospital shall be removed from participation in the pilot program by the department.

(g) Each pilot hospital shall provide quarterly reports to the department and the oversight committee that include statistical data and patient information relating to the number of elective PCI procedures performed, the interventionalists performing elective PCI procedures, and the outcomes of those procedures. In addition, pilot hospitals shall include in the report recommendations, if any, for modifications to the pilot program and any other information the pilot hospitals deem relevant for evaluating the success of the pilot program in delivering improved patient care. The department and the oversight committee may make site visits to any pilot hospital at any time.

(h) The department shall prepare and submit a report to the Legislature on the results of the Elective PCI Pilot Program. The report shall be submitted no later than 90 days after termination of the pilot program. The report shall include, but not be limited to, an evaluation of the pilot program's cost, safety, and quality of care. The report shall also include a comparison of elective PCI performed in connection with the Elective PCI Pilot Program, and elective PCI performed in hospitals with onsite cardiac surgery services. The report shall further recommend whether elective PCI without onsite cardiac surgery should be continued in California, and if so, under what conditions.

(i) The department may charge pilot hospitals a supplemental licensing fee, the amount of which shall not exceed the cost to the department of overseeing the pilot program.

(j) The department may contract with a professional entity with medical program knowledge to meet the requirements of this section.

(k) This section shall remain in effect only until January 1, 2014, allowing up to two years for implementation and at least three years during which the pilot program will be operational. As of January 1, 2014, this section is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

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